OCT 1 6 2008

K082402

SECTION 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of the 510(k) Premarket Notification for the Imaging Therapeutics OsDx Hip BMD System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

PREDICATE DEVICES

The Imaging Therapeutics OsDx Hip BMD System is substantially equivalent to FDA-approved predicate devices with regard to indications for use and technological characteristics. These predicate devices are:

Technological Characteristics and Indication for Use
• CTXA Hip: K002113 • Pronosco X-Posure System Bone Densitometer: K984178 • Hologic Hip Structural Analysis Software K061561

INTENDED USE

The OsDx Hip BMD System stand-alone software is intended to provide an estimate of the bone mineral density (BMD) of the proximal femur using digital antero-posterior hip or pelvis radiographic images. This information may be used by the physician in the assessment of fracture risk in conjunction with the World Health Organization ("WHO") criteria and to compare the derived BMD estimate with reference populations of young (20 – 39) and age matched normals to compute T-scores and Z-scores respectively.

PRODUCT DESCRIPTION

The OsDx Hip BMD System is a software package that provides an estimate of BMD based on analysis of data derived from scanned hip X-rays. The program utilizes a quantitative bone structural algorithm that measures a composite of weighted cortical and trabecular parameters in proximal femur projection radiographs from which total hip bone mineral density (BMD) is mathematically derived. Image analysis can take place remotely or at the point of care.

The results, expressed as gm/cm^2, can be used for comparison to a reference data base of young normals (T-score) or age-matched controls (Z-Score).

SUBSTANTIAL EQUIVALENCE

Use of the Term "Substantial Equivalence"

The term "Substantial Equivalence" is used in this submission within the confines of the statutory use in the FDA's evaluation of a Pre-Market Notification Submission. Any statement regarding Substantial Equivalence used in this submission relates only to whether the device that is the subject of this submission may be lawfully marketed in the United States without pre-market approval or reclassification, and should not be interpreted as an admission, or any kind or type of evidence, in any patent proceeding, including patent infringement litigation or proceeding before any Patent Office.

The present submission and statements therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in the submission, or its use, may be considered indistinct, from a patentability perspective, from any other device referred to in this sub mission.

Technological Characteristics

The technological characteristics (including anatomic site analyzed) of the OsDx Hip BMD System are substantially equivalent to those of the cited predicate devices. Standard x-ray images are scanned and evaluated to provide an estimate of BMD and a comparison to a normative data cohort for interpretation, including T-Score and Z-Score determination.

Indications for Use

Substantial equivalence is also supported for the OsDx Hip BMD System by the predicate devices previously cited and cleared in the treatment for the estimation of BMD.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

The device design was evaluated using standard methods for evaluation of BMD estimates in patient populations including patients across the spectrum of age. Software validation was performed using standard techniques.

SUMMARY

Based on the similarities in analytical approach, anatomic site evaluated and technological characteristics, the OsDx Hip BMD System is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. In addition OsDx Hip BMD System raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2008

Patrick Hess, Ph.D.
Chief Executive Officer
Imaging Therapeutics, Inc.
400 Seaport Court, Suite 250
REDWOOD CITY CA 94063

Re: K082402
Trade/Device Name: Imaging Therapeutics OsDx Hip BMD System
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: August 15, 2008
Received: August 20, 2008

Dear Dr. Hess:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K 082402

Device Name: Imaging Therapeutics OsDx Hip BMD SYSTEM

Indications for Use:

The OsDx Hip BMD System stand-alone software is intended to provide an estimate of the bone mineral density (BMD) of the proximal femur using digital antero-posterior hip or pelvis radiographic images. This information may be used by the physician in the assessment of fracture risk in conjunction with the World Health Organization ("WHO") criteria and to compare the derived BMD estimate with reference populations of young (20 – 39) and age matched normals to compute T-scores and Z-scores respectively.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-

CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082402